



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

5171 '02 MAY 29 P2:38

MAY 16 2002

Mr. Frederic Lou
Vice President
Colin Worldwide Corporation
P.O. Box 96
Tenafly, New Jersey 07670

Dear Dr. Lou:

This is in response to your letter of April 28, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Colin Worldwide Corporation is making the following claims, among others, for the product **Paecilomyces hepiali chen & Ganoderma**:

"Enhances recovery of sickness;"

"Assists in strengthening body after radiotherapy and chemotherapy."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to prevent diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

97S-0163

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Please contact us if you require further assistance.

Sincerely,



John B. Foret
Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New Jersey District Compliance, HFR-MA340

COLIN WORLDWIDE CORPORATION

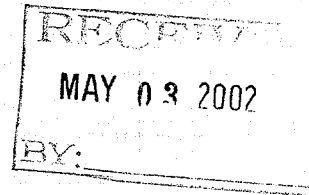
P.O. BOX 96
TENAFLY, NJ 07670
Tel: (201) 417-6006
Fax: (201) 568-1168

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April 28, 2002

FDA Office of Nutritional Products
Labeling & Dietary Supplements
Division of Standards & Labeling Regulation
HFS-820 5100 Paint Branch Parkway
College Park, MD 20740



Dear Sir Madam,

I will be importing and distributing within the US the following nutritional supplement. The ingredients and its uses will be as follows:

- 1) Paecilomyces hepiali chen & Ganoderma: 4gm granule packets, adenosine \geq .05%,
-Paecilomyces hepiali chen, Ganoderma, Fructus Lycii, Lactose, Steviosin, Dextrin
- 2) Paecilomyces hepiali chen & Ganoderma: 0.5gm capsule, adenosine \geq .20%
-Paecilomyces hepiali chen, Ganoderma, Fructus Lycii

Uses for this nutritional supplement:

- Promotes vitality and stamina
- Increases energy level
- Nourishes and enriches blood circulation as well as strengthening the body
- Enhances recovery of sickness
- Nourishes the kidney and liver
- Assists in strengthening body after radiotherapy and chemotherapy
- Enhances sexual function
- Helps in relaxation of body
- Enhances anti-oxidants system in the body
- Assists in memory stimulation
- Enhances immune system

I would very much appreciate your good comments regarding our supplement. I thank you so much in advance for your time and effort regarding this matter.

Sincerely,

Frederic Lou
Vice President
Colin Worldwide Corporation